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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,701	12/06/2005	Catherine Abbadie	21156YP	1960
210 7590 07/21/2009 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907				
EXAMINER				
PAGONAKIS, ANNA				
ART UNIT		PAPER NUMBER		
1614				
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07/21/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/559,701

Applicant(s)

ABBADIE ET AL.

Examiner

ANNA PAGONAKIS

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1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment filed 3/23/2009 has been received and entered into the present application.

Claims 2 and 4 are pending. Accordingly, claims 3 and 5 have been cancelled.

Applicant's arguments, filed 3/23/2009 have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Jaio et al (U.S. 7,230,008).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The claims encompass administering the elected compound to any patient for the prevention of neuropathic pain (as defined in page 3 of the specification). In order to prevent one must necessarily administer before the presence of disease and therefore administration of the elected compound in any patient population would then prevent neuropathic pain.

Jaio et al. teaches the administration of the elected compound for the treatment of inflammatory and immunoregulatory disorders (abstract and claims 1, 4-5 and 8-11).

Claims 2 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Jaio et al (U.S. 6,812,234).

The claims encompass administering the elected compound to any patient for the prevention of neuropathic pain (as defined in page 3 of the specification). In order to prevent one must necessarily administer before the presence of disease and therefore administration of the elected compound in any patient population would then prevent neuropathic pain.

Jaio et al. teaches the administration of the elected compound for the treatment of inflammatory and immunoregulatory disorders (column 14 and claims 1-24 and 25-27).

Claims 2 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Goble et al (U.S. 7,393,844).

The claims encompass administering the elected compound to any patient for the prevention of neuropathic pain (as defined in page 3 of the specification). In order to prevent one must necessarily administer before the presence of disease and therefore administration of the elected compound in any patient population would then prevent neuropathic pain.

Jaio et al. teaches the administration of the elected compound for the treatment of inflammatory and immunoregulatory disorders (column 14 and claims 1-22).

Claims 2 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Jaio et al (U.S. 7,166,614)

The claims encompass administering the elected compound to any patient for the prevention of neuropathic pain (as defined in page 3 of the specification). In order to prevent one must necessarily administer before the presence of disease and therefore administration of the elected compound in any patient population would then prevent neuropathic pain.

Jaio et al. teaches the administration of the elected compound for the treatment of inflammatory and immunoregulatory disorders (column 3 and claims 1-24).

Claims 2 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Butora et al (U.S. 7,390,803)

The claims encompass administering the elected compound to any patient for the prevention of neuropathic pain (as defined in page 3 of the specification). In order to prevent one must necessarily administer before the presence of disease and therefore administration of the elected compound in any patient population would then prevent neuropathic pain.

Jaio et al. teaches the administration of the elected compound for the treatment of inflammatory and immunoregulatory disorders (column 3 and claims 1-2).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would

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have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2 and 4 are provisionally rejected on the ground of nonstatutory double patenting over claims 1, 7 and 12 of copending Application No. 10/260,008 and claim 1 of copending Application No. 11/587,448. This is a provisional double patenting rejection since the claims have not yet been patented.

An obviousness-type double patenting rejection is appropriate where conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the patented claims and those of the present application are considered to be patentably distinct from each other. The reasons are as follows:

Both sets of claims are drawn to the use of the instantly claimed compounds. As discussed above, the claims encompass administering the elected compound to any patient for the prevention of neuropathic pain (as defined in page 3 of the specification). In order to prevent one must necessarily administer before the presence of disease and therefore administration of the elected compound in any patient population would then prevent neuropathic pain.

In view of the foregoing, the copending application claims and the current application claims are obvious variants.

Claims 2 and 4 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-5 and 8-11 of U.S. Patent No. 7,230,008 and claims 1-24

and 25-27 of U.S. Patent No. 6,812,234 and claims 1-22 of U.S. Patent No. 7,393,844 and claims 1-24 of U.S. Patent No. 7,166,614 and claims 1-2 of U.S. Patent No. 7,390,803.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are embraced by the patented claims.

Both set of claims are directed to use of the same compounds. Both sets of claims are drawn to the use of the instantly claimed compounds. As discussed above, the claims encompass administering the elected compound to any patient for the prevention of neuropathic pain (as defined in page 3 of the specification). In order to prevent one must necessarily administer before the presence of disease and therefore administration of the elected compound in any patient population would then prevent neuropathic pain.

In view of the foregoing, the compending application claims and the current application claims are obvious variants.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANNA PAGONAKIS whose telephone number is (571)270-3505. The examiner can normally be reached on Monday thru Thursday, 9am to 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AP

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614